

Certificate of analysis



Article	5351	Mupirocin-Calcium, mikronisiert, API (mikrob. Herkunft)	
Synonym		Mupirocinum calcicum	
Synonym		Mupirocin-Calcium, micronized, API(microbial origin)	
Batch	22001500		
Specification	Ph.Eur.10.3		
Production date	02.2021	Retest date	01.2026

Test	Specification	Result	
Characters	According to specification	Complies	
Appearance	According to specification	Complies	
Solubility	According to specification	Complies	
Identification	According to specification	Complies	
IR spectrophotometry	According to specification	Complies	
B	According to specification	Complies	
Tests	According to specification	Complies	
Specific optical rotation	-20 ... -16	-18	
Related substances	According to specification	Complies	#
Impurity C	Max. 2,5 %	0,8 %	#
Any other impurity	Max. 1 %	< 1 %	#
Total of all impurities	Max. 4,5 %	1,8 %	#
Chlorides	Max. 0,5 %	< 0,5 %	#
Water	3,0 ... 4,5 %	3,4 %	
Assay (anhydrous substance)	93,0 ... 102,0 %	97,9 %	#
Correction factor weighing (f, NRF)		1,022	
Complies specification		Yes	

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Release date	15.07.2022	Released by	Herr Apoth. Bartschat, QP, LQK
Manufacturer	TEVA Pharmaceutical Works Private Limite		
Manufacturer batch	83200340221		
Manufacturer street	Pallagi ut 13		
Manufacturer city	4042 Debrecen		
Manufacturer country	Ungarn		

GMP-compliant production and testing of the active pharmaceutical ingredients

Results marked with # were taken from the manufacturer's certificate.

The batch 22001500 complies specification.

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